

WHAT IS CLAIMED IS:

1. A method for determining the presence of host cell proteins in a sample, the method comprising:

5 (a) capturing host cell proteins from a sample onto a solid support with at least one affinity reagent that specifically binds host cell proteins; and,
(b) detecting the captured host cell proteins.

2. The method of claim 1, wherein the sample is selected from cell culture supernatant, organ extracts, a sample derived from a transgenic animal, a
10 sample derived from a transgenic plant, a sample derived from a transgenic egg or a biological fluid.

3. The method of claim 1, wherein the affinity reagent is selected from monoclonal antibodies, polyclonal antibodies, phage display proteins, aptamers, affibodies, chemical ligands, peptides, and combinations thereof.

15 4. The method of claim 1, wherein the affinity reagent comprises IgG immunoglobulins.

5. The method of claim 1, wherein the solid support comprises a protein biochip.

20 6. The method of claim 5, wherein the host cell proteins are detected by a gas phase ion spectrometry method, an optical method, an electrochemical method, atomic force microscopy, or a radio frequency method.

7. The method of claim 1, wherein the solid support comprises a surface enhanced laser desorption/ionization biochip on which the affinity reagent is immobilized before or after capturing the host cell proteins.

25 8. The method of claim 7, wherein surface enhanced laser desorption/ionization comprises applying a matrix material to the biochip before laser desorption/ionization.

9. The method of claim 7, wherein the surface enhanced laser desorption/ionization biochip comprises a surface-enhanced neat desorption surface.

10. The method of claim 1, wherein the solid support comprises a chromatographic resin.

5 11. The method of claim 10, wherein the resin comprises a material selected from ceramic, glass, metal, an organic polymer, and combinations thereof.

12. The method of claim 10, wherein detecting comprises washing unbound molecules from the resin, eluting the captured host cell proteins from the resin, and detecting the eluted host cell proteins.

10 13. The method of claim 10, wherein the solid support is a chromatographic resin derivatized with a capture molecule that binds the affinity reagent.

14. The method of claim 13, wherein the affinity reagent is an antibody and the capture molecule is Protein A, Protein G, or a mercaptoheterocyclic ligand.

15 15. The method of claim 1, wherein the host cell proteins are captured on a solid support derivatized with the affinity reagent.

16. The method of claim 1, wherein the host cell proteins are bound to the affinity reagent and the affinity reagent is subsequently captured on the solid support.

20 17. The method of claim 16, wherein the solid support is a surface enhanced laser desorption/ionization biochip derivatized with a capture molecule that binds the affinity reagent.

18. The method of claim 17, wherein the affinity reagent is an antibody and the capture molecule is Protein A, Protein G, or a mercaptoheterocyclic ligand.

25 19. The method of claim 1, wherein the host cell proteins are detected by mass spectrometry.

20. A method of following purification of a target protein comprising:

(a) profiling a sample comprising the target protein at one step of a purification process, wherein profiling comprises detecting the target protein in the sample and detecting host cell proteins in the sample using the method according to claim 1;

5 (b) subjecting the target protein to at least one purification step;

(c) profiling the sample comprising the target protein after the purification step, wherein profiling comprises detecting the target protein in the sample and detecting host cell proteins in the sample using the method according to claim 1; and,

(d) comparing the relative amounts of the target protein and the host cell

10 proteins in the sample detected by profiling.

21. The method of claim 20, wherein the target protein comprises a recombinant protein.

22. An article of manufacture comprising a solid support, at least one affinity reagent bound to the solid support, wherein the affinity reagent specifically binds host cell proteins and host cell proteins bound to the affinity reagent.

23. A kit comprising:

(a) a solid support derivatized with a reactive moiety or a capture molecule that specifically binds at least one affinity reagent; and,

(b) instructions to capture host cell proteins from a sample with the affinity

20 reagent, which affinity reagent specifically binds the host cell proteins, and to immobilize the captured host cell proteins on the solid support.